



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Parts 9 and 721**

**[EPA-HQ-OPPT-2013-0399; FRL-9941-56]**

**RIN 2070-AB27**

### **Significant New Use Rule on Certain Chemical Substances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is finalizing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for three chemical substances that were the subject of premanufacture notices (PMNs). This action requires persons who intend to manufacture (including import) or process any of the chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs.

**DATES:** This final rule is effective *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0399, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: [moss.kenneth@epa.gov](mailto:moss.kenneth@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Does this Action Apply to Me?**

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Manufacturers (including importers) or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance to a proposed or final rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is finalizing SNURs, under TSCA section 5(a)(2), for three very long chain chlorinated paraffin (vLCCPs - alkyl chain length of C<sub>21</sub> and above) chemical substances that were the subject of PMNs P-12-539, P-13-107, and P-13-109. This final rule requires

persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

In the **Federal Register** of August 7, 2013 (78 FR 48051) (FRL-9393-4), EPA issued direct final SNURs on these three chemical substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received notices of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), EPA removed the direct final SNURs in a separate final rule published in the **Federal Register** of November 5, 2013 (78 FR 66279) (FRL-9902-16), and issued a proposed rule in the **Federal Register** of February 10, 2014 (79 FR 7621) (FRL-9903-43). The record for the direct final SNURs on these chemical substances was established as docket EPA-HQ-OPPT-2013-0399. That docket includes information considered by the Agency in developing the proposed and final rules, including comments on the proposed rule.

EPA received several comments on the proposed rules for these three chemical substances, from a single commenter representing chlorinated paraffin (CP) manufacturers (including the submitter of the PMNs that are the subject of these SNURs). A full discussion of EPA's response to these comments is included in Unit V. of this document. After consideration of these comments, because the potential remains for increased exposure that formed the basis for the proposed SNURs, EPA is issuing the final rules as they were proposed for the chemical substances.

*B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors, listed in Unit IV. of this rule. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

### *C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the final rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

### **III. Rationale and Objectives of the Final Rule**

#### *A. Rationale*

During review of the PMNs submitted for the three chemical substances that are subject to these final SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health and environmental effects of the chemical substances. The basis for these findings is outlined in Unit IV of the proposed rule. Based on these findings, a TSCA section 5(e) consent order was negotiated with the PMN submitter that required manufacture of the substances at certain cumulative, aggregate volumes unless the company has submitted the results of certain environmental effects studies; no manufacture of the substances with the amount of chlorinated paraffins, with an alkyl chain less than or equal to 20, to exceed more than 1 percent of that PMN substance by weight; and risk notification. The SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent order. These final SNURs are issued pursuant to § 721.160. See the docket under docket ID number EPA–HQ–OPPT–2013–0399 for the corresponding consent order. For additional discussion of the rationale for the SNURs on these chemicals, see Units II., IV, and V. of the proposed rule.

#### *B. Objectives*

EPA is issuing final SNURs for three chemical substances described above to achieve the following objectives with regard to the significant new uses designated in this final rule:

- EPA will receive notice of any person's intent to manufacture or process a listed chemical substance for the described significant new use before that activity begins.

- EPA will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA will be able to regulate prospective manufacturers or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <http://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory>.

#### **IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substances listed in this final rule, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

## **V. Response to Comments on Proposed SNUR**

EPA received comments from the Chlorinated Paraffins Industry Association (CPIA), which represents the CP industry, including the submitter of the PMN substances that are the subject of these SNURs and other chlorinated paraffin manufacturers.

CPIA's comments, and associated attachments, can be found in the public docket under ID EPA-HQ-OPPT-2013-0399-0198.

*Comment 1:* Based on existing data and recent reviews, CPIA believes long chain chlorinated paraffin (LCCP - alkyl chain length of C<sub>18</sub> to C<sub>20</sub>) production and use in the U.S. present an extremely low risk to human health and the environment. Given this, CPIA questions the need for EPA to take specific action under TSCA Section 5(a)(2) for



any substances that could be considered LCCP. CPIA then provides information on why they believe LCCPs and vLCCPs do not present a risk.

*Response:* The comments primarily addressed the underlying risk assessments associated with the PMNs. EPA defers a discussion of the commenter's specific concerns as they are not relevant to the basis for determining that the uses specified in these SNURs constitute significant new uses. EPA is neither required to determine that a particular new use of any chemical substance presents, nor even that it may present, an unreasonable risk to human health or the environment. Rather, EPA issues a SNUR for a use of a substance if it is a significant new use (e.g., EPA has reason to anticipate that the use would raise significant questions related to potential exposure, so that the Agency should have an opportunity to review the use before such use should occur). EPA bases this judgment on a consideration of all relevant factors, including the specific factors identified at section 5(a)(2). Pursuant to TSCA section 5(a)(2), the PMN risk assessment does not serve as the basis for regulation of these SNURs, but as a valuable source of a breadth of information related to each substance's potential to threaten human health or the environment.

Nonetheless, EPA does have concern for these chemical substances because when released to the environment, vLCCPs are expected to rapidly partition to particulates and sediments where they are anticipated to persist in the environment with half-lives of months or greater. If they do degrade over time, these substances are expected to form shorter chain chlorinated chemicals. Based on the complex starting mixtures, lack of data on biological and abiotic reactions, and potential degradation products, there is high uncertainty regarding the fate and transport of these substances. Nevertheless, by analogy to medium chain chlorinated paraffins (MCCPs—alkyl chain length of C<sub>14</sub> to

C<sub>17</sub>) and LCCPs, EPA expects vLCCPs and possible degradation products to be potentially highly persistent, potentially highly bioaccumulative, and potentially toxic to aquatic and sediment-dwelling organisms. Further, within the category of vLCCPs, EPA expects the shorter carbon chain range of these substances (C<sub>21</sub> to C<sub>24</sub>) and lower chlorinated substances (degree of chlorination less than 50%) to present the greatest potential for risk, as they are expected to be the most bioaccumulative, mobile in the environment, and toxic. Transport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans. EPA has concerns about the potential for the vLCCPs to degrade to shorter chain chlorinated compounds, as well as concerns about potential impurities or small fractions of MCCPs and/or LCCPs.

MCCPs and LCCPs are expected to be PBT chemicals based on the following lines of evidence: a) The available data on MCCPs, sediment core studies, environmental fate studies, and associated calculations, indicate transformation half-lives of months to years, depending on the environmental media. Even though there are limited data on the LCCPs, biodegradation data indicated increasing stability with increasing chain length. LCCPs are also expected to have transformation half-lives comparable to, or greater than MCCPs. Therefore, MCCPs and LCCPs are expected to be very persistent; b) The available data on MCCPs and LCCPs indicate that these substances have bioconcentration factors (BCFs) and bioaccumulation factors (BAFs) that exceed 1,000 or 5,000 liters per kilogram wet weight of tissue (L/kg ww). Therefore, MCCPs and LCCPs are expected to be very bioaccumulative; c) The available data on MCCPs and LCCPs indicated acute and chronic toxicity to aquatic organism with effects levels below

10 milligrams per liter (mg/L) or 0.1 mg/L, depending on the species and MCCP and LCCP congener evaluated. Therefore, MCCPs and LCCPs are expected to be toxic to aquatic organisms; d) EPA is concerned about PBT chemicals because even small releases may persist in environmental media, build up in the environment and concentrate/accumulate in organisms over time. These properties increase the potential for continual exposure, and thus risk; and e) EPA expects there to be releases of the PMN substances to the environment resulting from distribution in commerce and during processing and all the substances' intended uses.

EPA notes that its risk assessments for certain MCCP and LCCP PMNs have recently been made available for public comment in the **Federal Register** of December 23, 2015 (80 FR 79886) (FRL-9940-13).

*Comment 2:* CPIA questioned the appropriateness of treating certain of the substances in the proposed SNUR as chemical analogs to LCCPs or vLCCPs, because two of the three substances covered by this SNUR are described as being "branched and linear" chloroalkanes: Alkanes, C<sub>21</sub> to C<sub>34</sub>-branched and linear, chloro, CAS Registry Number (CASRN) 1417900-96-9 (P-12-0539), and Alkanes, C<sub>22</sub> to C<sub>30</sub>-branched and linear, chloro, CASRN 1401974-24-0 (P-13-0107). CPIA could not find detailed compositional information about these substances in the rulemaking docket. Regardless, CPIA does not expect that anyone intending to make chlorinated paraffins would intentionally seek to make branched chloroalkanes. CP manufacturers have always used either *n*-paraffin or alpha-olefin feedstocks, both of which should be almost exclusively linear if they are to be used in CP manufacturing operations. To the extent that these hydrocarbon feedstocks contain branched or isoparaffin content, they are considered an impurity and something

to be minimized and closely controlled. The Organisation for Economic Cooperation and Development (OECD) Screening Information Dataset (SIDS) dossier and SIDS Initial Assessment Report (SIAR) for LCCP discuss LCCP isoparaffin content in its section on impurities and states that the amount should not be more than 1-2%. This is consistent with CPIA's understanding of the feedstocks used in LCCP manufacture. Only linear chloroalkanes are desired in commercial CP products and any branched chloroalkane (i.e. chlorinated isoparaffin) content is considered an impurity and should be kept to a minimum.

*Response:* EPA understands that some CPs may contain only linear chloroalkanes, but for these two "branched and linear" PMN submissions that EPA has received, the percent branching is greater than the 1-2% figure mentioned in the CPIA comments and the branching is thus part of the specific chemical name for TSCA Chemical Inventory purposes.

*Comment 3:* EPA has designated the PMN/SNUR substances as very long chain chlorinated paraffin (vLCCP), with a nominal carbon chain length of C<sub>21</sub> to C<sub>30</sub>. EPA has designated LCCP as C<sub>18</sub> to C<sub>20</sub> chloroalkanes, although in all other venues, including EPA's previous CP testing program, the OECD SIDS assessment, the European Union (EU) Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier, and other recent assessments, LCCP has been considered as C<sub>18</sub> to C<sub>30</sub>. Most of the recent LCCP assessments have evaluated LCCP as a category comprised of three main subcategories: C<sub>18</sub> to C<sub>20</sub> Liquid LCCP, C<sub>20</sub> to C<sub>30</sub> Liquid LCCP, and C<sub>20</sub> to C<sub>30</sub> Solid LCCP.

*Response:* EPA recognizes that CPIA does not agree with the EPA designations for LCCP vs. vLCCP. The designation/cut-off for LCCPs and vLCCPs represents the chain lengths potentially contained in the liquid chlorinated paraffins and waxy/solid chlorinated paraffins. These designations (i.e., the differentiation between C<sub>18-20</sub> and C<sub>20</sub> CPs) are consistent with those in other jurisdictions, e.g., Environment Canada (see Ref. 1). There are a series of interactions that the CP industry has had with EPA over the years, including TSCA section 4 test rules on specific TSCA chemicals and the Toxics Release Inventory (TRI). In previous actions under TSCA and TRI, the Agency has used a different naming convention, often based on public comment from industry. However, in each action the chemical substance that was the subject of the action has been clear because information such as chemical formula has been part of the identification. Previous attempts to divide chlorinated paraffins into various categories were based primarily on industrial usage patterns and industry comment, not on toxicological information.

Regardless of the naming conventions raised by the commenter, in reviewing the studies submitted with the PMNs in this SNUR and other PMNs, and the scientific literature more broadly, EPA has concluded that there is a continuum of effects linked to chain length and degree of chlorination. On the one end of the spectrum are SCCPs and MCCPs; more data are available on these chain lengths, and EPA has concluded that sufficient data exists to conclude that they may be PBTs. There are also some, albeit significantly less, data on the vLCCPs, most of which appear to point to a lack of effects, but the chemical composition of the test substances was poorly characterized. Ultimately, EPA is interested in specific fate and toxicity tests on vLCCPs

that elucidate the relationship between degree of chlorination and alkyl chain length. The testing schema is designed to minimize the burden of testing of complex mixtures with numerous congeners.

*Comment 4:* According to the commenter, in the United States, commercial LCCP products have generally been in either the C<sub>20</sub> to C<sub>30</sub> liquid or C<sub>20</sub> to C<sub>30</sub> solid subcategories, with C<sub>18</sub> to C<sub>20</sub> liquid LCCP products found mostly in the European market. Given the lack of C<sub>18</sub> to C<sub>20</sub> liquid LCCP products in the U.S. market, CPIA does not necessarily object to EPA's division of the existing category into LCCP and vLCCP. However, CPIA, believes that drawing a "bright line" at a carbon length of C<sub>20</sub> is questionable based on the toxicology and environmental fate data available. CPIA cites as support the conclusion of the OECD SIDS Initial Assessment Profile (SIAP) of LCCP, that "C20-30 liquid and solid LCCPs are of low concern for the environment based on their low hazard profiles....Adequate screening-level data are available to characterize the environmental hazard for the purposes of the OECD HPV (High Production Volume) Chemicals Programme."

*Response:* EPA recognizes that CPIA does not agree with the EPA designations for LCCP vs. vLCCP. EPA disagrees with CPIA that linear C<sub>18</sub> to C<sub>20</sub> CPs are not available within the United States, as EPA has received one or more PMN submissions for these types of CPs and therefore they may be commercially available. Further, these designations are consistent with those in other jurisdictions, e.g., Environment Canada (Ref. 1). Please refer to the response to Comment 1 for the issue of hazard and PBT discussions pertaining to chain length.

*Comment 5:* Limited information on EPA's assessment of vLCCP is provided in the proposed SNUR, associated Consent Order, and the rulemaking docket. Perhaps this limited information is due to the nature of this SNUR and the PMN review process.

*Response:* EPA reviewed the PMNs based on the contents of the PMN and information available on analogs and in the literature. As with all PMN submissions, EPA has followed the processes, procedures and statutory provisions of TSCA section 5 for the chlorinated paraffin PMNs, including EPA's Policy Statement on PBT New Chemical Substances (64 FR 60194; November 4, 1999; FRL-6097-7). EPA's assessment of exposures and risks for these three PMN substances is provided in Unit IV of the Preamble to the section 5(e) Consent Order (available in the public docket to the proposed rule) and is also presented in the response to Comment 1. Note that EPA has recently made available assessments for certain MCCP and LCCP PMNs, in the **Federal Register** of December 23, 2015 (80 FR 79886) (FRL-9940-13).

*Comment 6:* EPA indicates that it was unable to locate any chronic aquatic toxicity data on LCCP and as a consequence has relied solely on MCCP data. Further, EPA claims that based on these MCCP data there may be concerns regarding vLCCP's aquatic toxicity. EPA should be aware that there are both chronic fish and invertebrate toxicity data on various carbon chain length and chlorination level LCCP test materials. These were included in all of the recent reviews of LCCP, including the OECD SIDS assessment, the REACH registration dossier, and the U.K. LCCP Environmental Risk Assessment report.

*Response:* As noted in the TSCA section 5(e) Consent Order signed with the PMN submitter and available in the public docket, there were no valid chronic aquatic toxicity

data available for LCCPs or vLCCPs. EPA did consider the LCCP REACH Consortium aquatic toxicity database (see Attachment B in the CPIA comments), but the data were inadequate to allow EPA to identify a Concentration of Concern (COC). The studies tested concentrations in excess of the water solubility and did not analytically measure the concentrations that were in solution, which led to results orders of magnitude above the water solubility. Given the lack of reliable test data for the PMN substances listed in the SNUR, EPA used a read-across approach using MCCPs. The chronic aquatic toxicity test results and resulting COCs for MCCP data are within the estimated water solubilities and therefore these data are deemed reliable. The most reliable and acceptable studies indicate that, for vLCCPs, the predicted toxicity to aquatic organisms for acute endpoints are no effects at saturation. For the chronic toxicity endpoint, EPA used the aquatic invertebrate chronic value of 0.013 mg/L from the Thompson et al. 1997 study (Ref. 2) based on a MCCP material. This value was divided by an assessment factor of 10 to yield 0.0013 mg/L or 1.3 micrograms (µg)/L or 1.3 parts per billion (ppb).

*Comment 7:* CPIA readily acknowledges that, as EPA notes, toxicity to aquatic plant life and toxicity to sediment organisms are data gaps for LCCP. There have been several different approaches used to fill these data gaps. In the case of aquatic plant life, some testing has been done on LCCP toxicity to aquatic plant life though the reliability of these data has been called into question by reviewers and the data were not deemed sufficiently valid to address the endpoint. Most assessments of LCCP have thus considered read-across data from MCCP as being adequate to fill this data gap. The data from MCCP indicate that neither MCCP, nor LCCP by analogy, are toxic to aquatic plant life. Given this, CPIA supports the use of MCCP data in the assessment of LCCP/vLCCP.



*Response:* EPA agrees that toxicity to aquatic plant life is a data gap for LCCP/vLCCP and that MCCP serves as an appropriate analog in a read-across approach.

*Comment 8:* For LCCP sediment toxicity and risk, previous assessments by the U.K. Environment Agency and the REACH registration dossier have extrapolated from LCCP aquatic toxicity data to sediment toxicity using the equilibrium partitioning method. This approach is detailed in Attachment C of CPIA's comments, which is a direct excerpt from the U.K. Environment Agency's (EA) LCCP assessment. Given the very low water solubility of LCCP and the very high predicted  $K_{ow}$ , this method estimates rather high predicted no effect concentrations (PNECs) for LCCP. A PNEC is functionally similar to EPA's concentration of concern (CoC) in that both are points of departure for environmental risk assessment. The comparison between the sediment PNECs derived by the EA using the equilibrium partitioning method and the sediment CoC derived by EPA using an MCCP sediment toxicity study are orders of magnitude apart. Given this large difference and the fact that both methods have limitations, CPIA thinks that this may be a data gap to consider for additional testing of vLCCP assuming chemical analysis concerns can be addressed and only if exposure/release information actually dictate a need for this testing.

*Response:* EPA agrees that sediment toxicity is a data gap for vLCCPs. The most reliable and acceptable value for the toxicity to sediment invertebrate organisms is based on the MCCP material from the Thompson et al. 2002 study (Ref. 3). For vLCCPs, EPA used the 28-day sediment invertebrate Geometric Mean Acceptable Toxicant Concentration (GMATC) value of 187 mg/kg dry weight sediment as an analog approach to assess hazard. To calculate an acute concern concentration, this value is first multiplied by an

acute to chronic ratio for invertebrates of 10 to yield 1,870 mg/kg dry weight sediment, and then this value is divided by an assessment factor of 5 to yield 374 mg/kg dry weight sediment. For the chronic toxicity endpoint, EPA used the 28-day sediment invertebrate GMATC of 187 mg/kg dry weight sediment also from the Thompson et al. 2002 study. This value is divided by an assessment factor of 10 to yield 18.7 mg/kg dry weight sediment.

*Comment 9:* EPA states that vLCCP by analogy to MCCP may be "potentially highly persistent, potentially bioaccumulative and potentially toxic." EPA further indicates that, "[t]ransport and magnification across trophic levels may also result in toxicity to higher organisms, including fish, higher predators, and potentially humans," though it is not clear whether this statement is directed at vLCCP or MCCP as an analog. Regardless, EPA should be aware there has been considerable research done in recent years on the environmental fate of MCCP, including new research on biodegradation and the potential for bioaccumulation, including trophic magnification potential.

*Response:* EPA has reviewed all the information cited by CPIA, including the specific biodegradation studies described in the comments and biodegradation studies on LCCPs. No persistence or bioaccumulation data were available or submitted to EPA for the commercial Unknown or Variable composition, Complex reaction products and Biological materials (UVCB) multicomponent substances described in the PMNs. In the absence of data on the commercial UVCB substances, EPA used data on their components, analogs and used a read-across approach. EPA notes that close analogs of MCCPs are the short chain chlorinated paraffins (SCCPs) which have been proposed for addition to the Stockholm Convention on Persistent Organic Pollutants.

*Comment 10:* Given the available data, CPIA believes that any analogy to MCCP for vLCCP must consider that while lower chlorinated CP substances may have somewhat greater capacity to bioaccumulate – though bioaccumulation will also decrease significantly with increasing carbon chain length – these same lower chlorinated CPs show a greater potential to biodegrade. In fact, MCCP constituents up to 50% chlorination have been found to be readily biodegradable and therefore are not persistent, bioaccumulative, and toxic chemicals (PBTs). Higher chlorinated MCCP constituents also showed significant potential to biodegrade though the results did not reach the "ready" criteria. Perhaps even more telling is the fact that field studies have not shown MCCP to biomagnify across trophic levels (Ref. 4). CPIA believes that vLCCP, which is less soluble in water and less bioavailable than MCCP, will have even less potential to move up through the troposphere and biomagnify. This conclusion was similarly reached by the U.K. Environment Agency (Ref. 5), the OECD (Ref. 6), and the European Chemical Bureau (ECB) PBT Working Group (Ref. 7).

*Response:* EPA has reviewed all the information cited by CPIA including the specific bioaccumulation/biomagnification studies described in the comments. No persistence or bioaccumulation data were submitted for the commercial UVCB multicomponent substances described in the PMNs. In the absence of data on the commercial UVCB multicomponent substance, EPA used data on components of that substance, structural analogs and a read-across approach. Although bioaccumulation data are lacking with vLCCPs, there is still concern for the presence of lower chain length and moderately chlorinated components in the vLCCP commercial UVCB multicomponent substance that have the potential to be both persistent and bioaccumulative. EPA considered more

recent reviews of the bioaccumulation potential of MCCPs by Thompson and Vaughn (Ref. 4) and Arnot (Ref. 8) in making the determination that MCCPs may be very bioaccumulative. The framework for assessing bioaccumulation outlined by Gobas et al. (Ref. 9) describes a preferred data hierarchy that places field Trophic Magnification Factor (TMF) studies at the top. EPA recognizes that there are significant uncertainties associated with the available TMF data for MCCPs. In the absence of such data, the framework outlines the use of bioconcentration factors (BCFs), bioaccumulation factors (BAFs), and biomagnification factors (BMFs) to be considered with caution. EPA believes that its review of available data on the bioaccumulation potential of MCCPs is consistent with the approach described by Gobas et al. (Ref. 9) and that the data support its finding that MCCPs may be very bioaccumulative and by analogy so may vLCCPs.

*Comment 11:* CPIA is concerned that EPA's proposed testing approach for vLCCP in the proposed SNUR (Attachment A of CPIA's comments) fails to consider the highly complex nature of the LCCP/vLCCP UVCB substances and the analytical limitations inherent to this complex composition. For example, even a single carbon-chain length straight-chain chloroalkane, will have tens of thousands or more possible isomers. Tomy et al. (Ref. 10) calculated that for a C<sub>13</sub> chloroalkane at 60% chlorination by weight, the total number of possible isomers is 3,549, even assuming no more than one chlorine atom bound to an individual carbon atom. This number of theoretical isomers more than doubles with each added carbon number, suggesting that by C<sub>21</sub>, the lowest carbon chain length that EPA has proposed testing, this test material could have hundreds of thousands of possible isomers.

*Response:* EPA understands the complexity of vLCCPs and therefore stipulates under the consent order for the PMN substances the testing of three specific chain lengths and chlorination levels. EPA expects that a single chain length at a specific chlorination level can be produced. The purpose of the sequence of testing, i.e., biodegradation testing and identification of degradation products followed by bioaccumulation testing and benthic toxicity testing, is to use the results of the biodegradation tests to identify biodegradation products. The selection of three less complex congener PMN surrogates for testing reduces the analytical complexities associated with characterization of the test substance and identification of products formed during biodegradation testing.

*Comment 12.* Current guidance from manufacturers indicates that vLCCP substances should not be released to surface water and/or poured down the drain. When this guidance is applied to exposure models, the predicted releases levels to surface water and corresponding concentrations in sediment are below the levels of concern.

*Response:* While the SNUR is not based on EPA's risk assessment, EPA notes that information regarding releases of vLCCPs was submitted to EPA by the PMN submitter of these three SNUR substances and is used in the risk assessment. EPA's risk assessment for the PMN substances indicated that releases of the substances may occur and that without the less than 1 weight percent of chlorinated paraffins with an alkyl chain  $\leq 20$  manufacturing restriction, those releases may pose an unreasonable risk to the environment. Further, apart from any risk resulting from releases assessed for the PMN chemical substance, chlorinated paraffins with alkyl chain lengths  $\leq 20$  are very persistent and very bioaccumulative toxic chemical substances. Thus a SNUR is important because it gives EPA an opportunity to review and evaluate data on the

significant new use before it commences. These significant new use may have release and exposure profiles that are different from that considered in the PMN.

To the extent that the commenter is suggesting that the predicted releases to surface water do not present a risk and thus do not support a significant new determination, EPA notes that a significant new use determination is not based on risk.

## **VI. Applicability of the Significant New Use Designation**

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing. Consult the **Federal Register** notice of April 24, 1990 (55 FR 17376, FRL 3658-5) for a more detailed discussion of the cutoff date for ongoing uses.

Any person who began commercial manufacture or processing of the chemical substances identified in this rule for any of the significant new uses designated in the proposed SNUR after the date of publication of the proposed SNUR, must stop that activity before the effective date of the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

## **VII. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing.

Recommended testing that would address the criteria of concern of § 721.170 can be found in Unit IV. of the proposed rule. Descriptions of tests are provided only for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.

- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VIII. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and 720.40. E-PMN software is available electronically at <http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn>.

## **IX. Economic Analysis**

EPA evaluated the potential costs of SNUN requirements for potential manufacturers and processors of the chemical substances in the rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2014-0390

## **X. References**

The following is a listing of those documents used to prepare the preamble to this final rule. Additional information for this final rule can be located under docket ID number EPA-HQ-OPPT-2013-0399, which is available for inspection as specified under **ADDRESSES**.



1. Environment Canada, August 2008. Canadian Environmental Protection Act, 1999 Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health: Chlorinated Paraffins.
2. Thompson, R. S., N. J. Williams, and E. Gillings. 1997. *Chlorinated Paraffin (52% Chlorinated, C<sub>14</sub>-C<sub>17</sub>): Chronic Toxicity to Daphnia Magna*. AstraZeneca Confidential Report, BL 5791/B.
3. Thompson, R. S., D. V. Smyth, and E. Gillings. 2002. *Medium-Chain Chlorinated Paraffin (52% Chlorinated, C<sub>14</sub>-C<sub>17</sub>): Effects in Sediment on the Survival, Growth and Sexual Development of the Freshwater Amphipod, Hyalella Azteca*. AstraZeneca Confidential Report BL7469/B.
4. Thompson, Roy and Martin Vaughn. 2014. Medium-chain chlorinated paraffins (MCCPs): A review of bioaccumulation potential in the aquatic environment. Integrated Environmental Assessment and Management. Volume 10, Issue 1, pages 78–86, January 2014.
5. U.K. Environment Agency (EA). 2009. Environmental Risk Evaluation Report: Long-Chain Chlorinated Paraffins. January 2009.
6. Organisation for Economic Cooperation and Development (OECD). 2009. SIDS Initial Assessment Report (SIAR) and SIDS Initial Assessment Profile (SIAP) for Long Chain Chlorinated Paraffins (LCCPs). Reviewed and approved at SIAM-29, October 20-23, 2009.
7. European Chemicals Bureau (ECB) PBT Working Group. 2007. Results of the Evaluation of the PBT/vPvB Properties of Paraffin waxes and Hydrocarbon waxes, chlor; EC number 264-150-0; CAS number 63449-39-8. PBT List No. 110. September 11, 2007.
8. Arnot, Jon. 2013. Comments on Preliminary Bioaccumulation Assessment of Medium Chain Chlorinated Paraffins (MCCPs): Prepared for the MCCP REACH Consortium. April 30, 2013.

9. Gobas, Frank APC; Watze de Wolf; Lawrence P. Burkhard; Eric Verbruggen; Kathleen Plotzke. 2009. Revisiting Bioaccumulation Criteria for POPs and PBT Assessments. *Integrated Environmental Assessment and Management* 5(4): 624-637.
10. Tomy, Gregg T.; Gary A. Stern, Derek C. G. Muir, Aaron T. Fisk, Chris D. Cymbalisky, and John B. Westmore. 1997. Quantifying C10-C13 Polychloroalkanes in Environmental Samples by High-Resolution Gas Chromatography/Electron Capture Negative Ion High-Resolution Mass Spectrometry. *Analytical Chemistry* 69: 2762-2771.

## **XI. Statutory and Executive Order Reviews**

### *A. Executive Order 12866*

This final rule establishes SNURs for chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “*Regulatory Planning and Review*” (58 FR 51735, October 4, 1993).

### *B. Paperwork Reduction Act (PRA)*

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and

their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

*C. Regulatory Flexibility Act (RFA)*

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this final rule.

This final rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VIII. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not

have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132*

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

*F. Executive Order 13175*

This action does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this final rule.

*G. Executive Order 13045*

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by

Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211*

This action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

*J. Executive Order 12898*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

**XII. Congressional Review Act (CRA)**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 5, 2016.

Maria J. Doa,

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*



Therefore, 40 CFR Parts 9 and 721 are amended as follows:

**PART 9--[AMENDED]**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, add the following sections in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

**§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

40 CFR citation	OMB control No.
* * * * *	
<b>Significant New Uses of Chemical Substances</b>	
* * * * *	
721.10673	2070-0012
721.10674	2070-0012
721.10675	2070-0012

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\* \* \* \*

## **PART 721--[AMENDED]**

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Add § 721.10673 to subpart E to read as follows:

### **§ 721.10673 Alkanes, C21-34-branched and linear, chloro.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C21-34-branched and linear, chloro (PMN P-12-539; CAS No. 1417900-96-9) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in §721.80 (j)(manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain  $\leq 20$ ) and (p) (1,200,000 kg, 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg of the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109, from the March 19, 2013 effective date of the TSCA section 5(e) consent order for P-12-539, P-13-107, and P-13-109).).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

5. Add § 721.10674 to subpart E to read as follows:

**§ 721.10674 Alkanes, C22-30-branched and linear, chloro.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C22-30-branched and linear, chloro (PMN P-13-107; CAS No. 1401947-24-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (j)(manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain  $\leq 20$ ) and (p) (1,200,000 kg, 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg of the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109, from the March 19, 2013 effective date of the TSCA section 5(e) consent order for P-12-539, P-13-107, and P-13-109).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

6. Add § 721.10675 to subpart E to read as follows:

**§ 721.10675 Alkanes, C24-28, chloro.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C24-28, chloro (PMN P-13-109; CAS No. 1402738-52-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (j) (manufacture of the PMN substance with less than 1 weight percent of chlorinated paraffins with an alkyl chain  $\leq 20$ ) and (p) (1,200,000 kg, 14,100,000 kg, 59,100,000 kg, 78,400,000 kg, and 86,100,000 kg of the aggregate of the PMN substances P-12-539, P-13-107, and P-13-109, from the March 19, 2013 effective date of the TSCA section 5(e) consent order for P-12-539, P-13-107, and P-13-109).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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